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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FITZPATRICK CELLA HARPER & SCINTO
30 ROCKERFELLER PLAZA
NEW YORK, NY 10112-3801

EXAMINER
ARTHUR, LISA BENNETT

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/581,478	Applicant(s) ISHIDA, TAKUYA	
	Examiner Lisa B. Arthur	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *03 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-21 and 23-38* is/are pending in the application.

4a) Of the above claim(s) *1,8-19 and 23-38* is/are withdrawn from consideration.

5)☐ Claim(s) *2,3,5 and 6* is/are allowed.

6)☐ Claim(s) *4,7,20,21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. This action is in response to the paper filed June 3, 2002. Claim 22 has been canceled, and claims 2 and 4 have been amended. Currently, claims 1-21 and 23-38 are pending but claims 1, 8-19 and 23-38 have been withdrawn from consideration by the restriction requirement made in the office action mailed October 3, 2001. The action contains and examination of claims 2-7, 20 and 21. All of the amendments and arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons that follow. Any rejections which have not been reiterated have been withdrawn in view of the amendments. This action contains new grounds of rejection which have been necessitated by the amendment of the claims. This action is FINAL.

MAINTAINED REJECTION

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 4, 20 and 21 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kitamura et al.

Kitamura et al. teach a DNA encoding rat NapI which is a protein which is 99.4% similar in amino acid sequence to the amino acid sequence of SEQ ID NO 2. Kitamura et al. Teach that this DNA was isolated from rat brain tissue. The coding sequence is of identical length, i.e. 1128 amino acids, and is different at only 6 amino acids, 5 of which are conservative amino acid differences. The DNA of Kitamura et al. is 68% similar over all with regions of 91% similarity to the nucleotide sequence of SEQ ID NO 1. The DNA of Kitamura et al., therefore is

sufficiently similar to the DNA of SEQ ID NO 1 to hybridize under stringent conditions, and because of this very high degree of sequence similarity of the protein sequences can be reasonably assumed to have apoptosis suppressing activity.

Response to Arguments

The response traverses the rejection on the grounds that Kitamura et al. does not teach a DNA which has 95% or more homology with the nucleotide sequence of claims 2 or 3. This argument is not convincing because while the DNA of Kitamura et al. is not 95% homologous to the DNA of SEQ ID NO 1 it is 95% homologous with a DNA encoding SEQ ID NO 2. A DNA encoding SEQ ID NO 2 encompasses every degenerate variant of SEQ ID NO 2 including a degenerate in which every codon is alerted a at least one position as a long as the codon encodes the same amino acid. Such a degenerate DNA would still encode the amino acid sequence of SEQ ID NO 2 would be only about 60% similar to the nucleotide sequence of SEQ ID NO 1. Consequently, since the claims are drawn to DNAs which hybridize to a DNA encoding SEQ ID NO 2 and since the DNA of Kitamura et al. is 68% similar to the sequence of SEQ ID NO 1, the DNA of Kitamura et al. still anticipates the broadly claimed invention.

4. Claims 4, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartener et al. Baumgartener et al. Teach a DNA encoding a protein which is 99.4% similar in amino acids seqeunce to the amino acid sequence of SEQ ID NO 2. Baumgartener teach that his protein is part of a family of protein, the HEM proteins, that are tissue specific transmembrane proteins expressed in invertebrates through mammals and which are essential in oogenesis. Baumgartener et al. Teach that this DNA was isolated from rat brain tissue. The

coding sequence is of identical length, ie.e. 128 amino acids and is different at only 6 amino acids, 5 od which are coservative amino acid differences. The DNA of Baumgartener et al. is 68% similar over all with regions of 91% similarity to the nucleotide sequence of SEQ ID NO 1. The DNA of Baumgartener et al., therefore is sufficiently similar to the DNA of SEQ ID NO 1 to hybridize under stringent conditions, and because of this very high degree of sequence similarity of the protein sequences can be reasonably assumed to have apoptosis suppressing activity.

Response to Arguments

The response traverses the rejection on the grounds that Baumgartener et al. does not teach a DNA which has 95% or more homology with the nucleotide sequence of claims 2 or 3. This argument is not convincing because while the DNA of Baumgartener et al. is not 95% homologous to the DNA of SEQ ID NO 1, it is 95% homologous with a DNA encoding SEQ ID NO 2. A DNA encoding SEQ ID NO 2 encompasses every degenerate variant of SEQ ID NO 2 including a degenerate in which every codon is alerted a at least one position as a long as the codon encodes the same amino acid. Such a degenerate DNA would still encode the amino acid sequence of SEQ ID NO 2 would be only about 60% similar to the nucleotide sequence of SEQ ID NO 1. Consequently, since the claims are drawn to DNAs which hybridize to a DNA encoding SEQ ID NO 2 and since the DNA of Baumgartener et al. is 68% similar to the sequence of SEQ ID NO 1, the DNA of Baumgartener et al. still anticipates the broadly claimed invention.

NEW GROUNDS OF REJECTION

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 4, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitamura et al. in view of Nagase et al. (DNA Research 5: 31-39 (1998).

This rejection is directed to DNAs which can hybridize to a DNA which has 95% homology to SEQ ID NO 1.

Kitamura et al. teach a DNA encoding rat NapI which is a protein which is 99.4% similar in amino acid sequence to the amino acid sequence of SEQ ID NO 2. Kiramura et al. Teach that this DNA was isolated from rat brain tissue. The coding sequence is of identical length, i.e. 1128 amino acids, and is different at only 6 amino acids, 5 of which are conservative amino acid differences. The DNA of Kitamura et al. is 68% similar over all with regions of 91% similarity to the nucleotide sequence of SEQ ID NO 1. The DNA of Kitamura et al., therefore is sufficiently similar to the DNA of SEQ ID NO 1 to hybridize under stringent conditions, and

because of this very high degree of sequence similarity of the protein sequences can be reasonably assumed to have apoptosis suppressing activity. Kitamura et al. Also taught that rat NapI was isolated by its ability to bind to human Nck protein known to be an oncoprotein. Kitamura et al. Taught that binding proteins of the SH3 domains of Nck have been sght because of their suspected role is transmitting Ras-dependent signals. (abstract).

The DNA of Kitamura et al. does not have 95% or more homology with the nucleotide sequence of SEQ ID NO 1 or the nucleotide sequence encoding SEQ ID NO 2.

However, Kitamura et al. taught that rat NapI was isolated from rat brain cDNA using a mouse brain cDNA clone that had partial similarity to the rat NapI sequence as a probe in a colony hybridization assay (page 510, paragraph 2 and page 511, paragraph 2)

Furthermore, Nagase et al. teach the identification of coding sequences in human brain cDNA libraries by selecting clones having unidentified sequences at both termini and clones which produced proteins of 50 kDa or more in in vitro transcription/translation sustems. These clones were then sequenced.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have substituted the rat brain cDNA library of Kitamura et al. with the human brain cDNA library of Nagase et al. and have substituted the mouse brain cDNA probe used by Kitamura et al. with the rat Nap I cDNA of Kitamura et al. in order to have achieved the expected benefit of isolating the human NapI DNA homolog of Kitamura's rat NapI DNA and thereby making the claimed invention as a whole. The ordinary artisan would have been motivated to have used the rat NapI DNA as a probe to isolate the human NapI homolog because Kitamura et al. taught that Nck binding proteins were expected to be involved in ras

mediated cancers. While it would not have been obvious to have obtained a nucleic acid consisting of SEQ ID NO 1, the claims are broadly drawn to DNAs which are 95% homologous to SEQ ID NO 1 or DNA encoding SEQ ID NO 2. The ordinary artisan would have had a reasonable expectation that a human homolog having a 95% similar sequence to SEQ ID NO 1 would be isolated using the rat NapI coding DNA as a probe because Kitamura et al. taught that regions of the NapI rat and mouse protein were sufficiently homologous to allow hybridization and because the rat NapI protein was able to bind to human Nck protein suggesting a high degree of similarity between rat and human proteins.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 7, 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 4,20 and 21 are indefinite over the recitation of "said DNA" in the third line of claim 4 because the claims are unclear as to whether this term is referring to "A DNA capable of hybridizing ..." in line 1 or to "the DNA according to claim 2 or 3" in line 2. The scope of the claim is different depending upon which interpretation is relied upon.

B) Claim 7 as amended is indefinite over the recitation of "which includes a substitution , deletion or addition of one or more amino acids f the amino acid sequence of SEQ ID NO 2" because claim 2 from which claim 7 depends no longer contains this recitation.

8. Claims 2,3,5 and 6 are allowable over the prior art because they are limited to a DNA encoding SEQ ID NO 2 and a DNA having the nucleotide sequence of SEQ ID NO 1 neither of which is taught by the prior art. Kitamura and Baumgartner et al. teach the rat Nap1 nucleotide and protein sequence which are 99.4% and 68% similarly, respectively to the disclosed human NapI protein and nucleotide sequence. Neither Kitamura et al nor Baumgartner et al. taught or suggested a DNA having the specific sequence of SEQ ID NO 1 or a DNA encoding the specific amino acid sequence of SEQ ID NO 2. While it would have been obvious to have looked for the human NapI DNA using the rat NapI DNA as a probe, it would not have been obvious to have obtained the specifically claimed DNA sequences because the ordiary artisan would have had no idea where the alterations would have occurred in the sequence of Kitamura or Baumgartner to make the sequences of SEQ ID Nos 1 or 2.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa B. Arthur whose telephone number is (703) 308-3988. The examiner can normally be reached on Monday and Tuesday from 7:00am to 3:30 pm. The examiner can also be reached on alternate .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Lisa B. Arthur

LISA B. ARTHUR
PRIMARY EXAMINER
GROUP 1800 1600

August 5, 2002